

Application Serial No. 09/764,630  
Response dated November 4, 2004  
Reply to Office Action dated August 4, 2004

### **REMARKS**

Following this Amendment, claims 1-13 are pending. Claims 1-12 have been rejected. Claim 1 has been amended. Claim 7 has been canceled. Claim 13 has been added. Applicants further note that claim 2 was cancelled by the Applicants in the submission with the RCE submitted on July 1, 2004. Thus, Applicants submit that the rejection of claim 2 by the Examiner in the present Office Action is moot. In this response, Applicants respond to the rejections of claims 1 and 3-12.

#### **Claim Rejections - 35 U.S.C. § 102**

##### **Nightingale (U.S. Patent No. 3,747,479)**

The Examiner has rejected claims 1-7 and 12 of the present application under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,747,479, issued to Nightingale. The Examiner's rationale for rejecting claims 1-7 and 12 as anticipated by Nightingale is as follows: The Examiner states that Nightingale discloses a syringe capable of mounting to an injector, including a barrel, plunger with rearwardly facing drive ram engaging coupling element that is knurled, a discharge tip, a conical front wall, syringe mating sections including annular flange, and an interior cavity within the coupling element. The Examiner further states that the area adapted to be within an area enveloped by a coupling mechanism exhibits no discontinuity in area. In view of the present amendment to independent claim 1, Applicants respectfully disagree with the rejection under 35 U.S.C. § 102.

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Applicants note that claim 1, as presently amended, recites that the rearwardly facing extension is knurled "at least along the portion of said extension adapted to be within an area enveloped by a coupling mechanism." Applicants submit that it is clear from the figures of Nightingale, and particularly Fig. 7, that the knurled portion of the component that the Examiner cites as the rearwardly facing extension is not "adapted to be within an area enveloped by a coupling mechanism." Rather, the mechanism that is coupled to the extension in Nightingale is the operating bar 79 and mandrel 73 (as seen in Fig. 7 of Nightingale), which extends through the interior of the extension 72. Thus, quite opposite to that recited in claim 1, the extension of Nightingale envelopes the coupling mechanism, rather than the coupling mechanism enveloping the knurled extension. Applicants thus submit that claim 1 as presently amended is not anticipated by Nightingale. Since claim 1 is not anticipated by Nightingale, Applicants further submit that dependent claims 2-6 are also not anticipated by Nightingale. Applicants further note that claim 7 has been presently canceled, and so the rejection of claim 7 over Nightingale is moot. Applicants therefore respectfully request a withdrawal of the rejection of claims 1-7 over Nightingale under 35 U.S.C. § 102(b).

Turning now to the rejection of claim 12 over Nightingale, Applicants note that claim 12 recites a rearwardly facing extension "wherein no two adjacent transverse cross-sections of said rearwardly facing extension exhibit discontinuity in area when

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compared to one another along the portion of said extension adapted to be within an area enveloped by a coupling mechanism." In short, claim 12 requires that the extension exhibit no discontinuities. Applicants note that the rearward facing element of Nightingale does include a discontinuity along its length. Thus, Applicants submit that Nightingale fails to disclose each and every claimed element of the present application as recited in claim 12. Applicants thus submit that claim 12 is not anticipated by Nightingale. Applicants therefore respectfully request a withdrawal of the rejection of claim 12 under 35 U.S.C. § 102(b).

**Reilly (U.S. Patent No. 4,677,980)**

The Examiner has further rejected claims 1 and 3-6 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,677,980, issued to Reilly. Applicants respectfully disagree.

As noted above with respect to the rejection of claim 1 under Nightingale, Applicants note that claim 1, as presently amended, recites that the extension is knurled along at least a portion that is adapted to be enveloped by a coupling mechanism. Applicants submit that Reilly does not disclose a coupling element on a plunger that is knurled along a portion adapted by a coupling mechanism. Only in Figs. 17 and 20, for example, does Reilly show a coupling mechanism enveloping a rearward facing extension. However, Applicants submit that the rearward facing extension of Figs. 17 and 20 is not knurled. And only Fig. 17 shows structures on the surface of the

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extension (Fig. 20, by contrast, shows a smooth extension). However, the structures on the extension of Fig. 17 are not knurls.

Referring to Fig. 17 and the disclosure at column 10, lines 4-31,

Applicants submit that the structures shown in Fig. 17 on the extension are a plurality of raised screw-type threads (160), which define a plurality of incline channels (162) therebetween. The screw-type threads (160) are designed to interact with a hook member (170), which is fixedly mounted on the right angle member of a hook assembly (166) of the coupling mechanism (also shown in Figs. 18 and 19). In use, as the drive mechanism, including the coupling mechanism, is advanced by the drive piston, the hook-shaped members (170) enter respective one of the channels (162) between the screw threads (160). As this happens, the hook members pass through the channels. Eventually, the outer ends of the hook assemblies (166) engage the extension on the plunger. In other words, the configuration of hooks on the coupling mechanism and threads on the extension engage to form a locking mechanism to hold the syringe plunger to the drive ram. This sort of positive engagement locking is completely different from the function provided by knurls. Applicants submit that knurls simply provide a roughened surface to increase friction in order to enhance the grip of a coupling mechanism. Thus, knurls are not described in the text of Reilly, nor shown in the Figures. Applicants thus submit that Reilly fails to disclose each and every claimed element of the present application in claim 1, as presently amended. Applicants thus

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submit that claim 1 is not anticipated by Reilly. Since claim 1 is not anticipated, Applicants further submit that dependent claims 3-6 are also not anticipated by Reilly. Applicants therefore respectfully request a withdrawal of the rejection of claims 1 and 3-6 as being anticipated by Reilly under 35 U.S.C. § 102(b).

**Densmore (U.S. Patent No. 5,007,904)**

The Examiner has further rejected claims 1 and 3-7 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,007,904, issued to Densmore. Applicants respectfully disagree.

As noted above with respect to the rejection of claim 1 under Nightingale, Applicants note that claim 1, as presently amended, recites that the extension is knurled along at least a portion that is adapted to be enveloped by a coupling mechanism. Applicants submit that Densmore does not disclose a coupling element on a plunger that is enveloped by a coupling mechanism. Rather, Densmore shows a rearward facing extension that envelopes a coupling mechanism rather than a coupling mechanism enveloping the knurled element. Applicants thus submit that Densmore fails to disclose each and every claimed element of the present application in claim 1, as presently amended. Applicants thus submit that claim 1 is not anticipated by Densmore. Since claim 1 is not anticipated, Applicants further submit that dependent claims 3-6 are also not anticipated by Densmore. Applicants further note that claim 7

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has been presently canceled, and thus the rejection of claim 7 is rendered moot.

Applicants therefore respectfully request a withdrawal of the rejection of claims 1 and 3-7 as being anticipated by Densmore under 35 U.S.C. § 102(b).

**Claim Rejections Double Patenting**

The Examiner has rejected claims 1-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 9 of U.S. Patent No. 6,196,999. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because they each recite a plunger with a knurled, rearwardly facing engaging coupling element that is for mounting to an injection within the syringe. Applicants respectfully disagree with the rejection for obviousness-type double patenting.

Applicants first note that the nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent, and to present possible harassment by multiple assignees. *In re Goodman*, 11 F.3d 1046, 29 USPQ 2d 2010 (Fed. Cir. 1993). In order to overcome the double patenting rejection, one may file a terminal disclaimer, such as in the present application, to ensure that the term of any patent arising from the present application does not extend beyond the life of U.S. Patent No. 6,196,999 (the '999 patent). However, Applicants note that the present application is a divisional of the '999 patent, and was filed in

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response to a restriction requirement issued by the U.S. Patent and Trademark Office.

With that in mind, Applicants note that 35 U.S.C. § 121, concerning divisional applications, recites in pertinent part:

"A patent issuing on an application with respect to which a requirement for restriction under this Section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application, or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application." (Emphasis added.)

Applicants submit that this section precludes the entry of a double-patenting rejection of claims of a divisional application filed subsequent to, and in conformance with, a restriction requirement in the parent application, over the claims of a patent issuing on the parent application.

This is the very situation here. The originally-filed independent claims of the present application are identical to those filed in the application issuing as the '999 patent case, but which were subjected to a restriction requirement issued from the U.S. Patent and Trademark Office. As a result of that restriction requirement, the present divisional application was filed. And the present divisional application was filed prior to the issuance of the parent '999 patent, which the Examiner now cites. However, 35 U.S.C. § 121, as quoted above, makes clear that in such a situation, the parent '999 patent may not be used as a reference against the present application. Applicants thus

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respectfully request a withdrawal of the double patenting rejection of claims 1-12 of the present application.

**Conclusion:**

For the foregoing reasons, it is submitted that all claims are patentable and a Notice of Allowance is respectfully requested.

It is believed that no fee is due. If, however, any additional fee or surcharges are deemed due, please charge same or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,

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